K050628

APR 7 2005

Exhibit 16-01

510(k) SUMMARY: –

CLASSIFICATION NAME: Powered simple cranial drills, burrs trephines and their accessories

COMMON/USUAL NAMES: Nosepiece attachment; nose-tube; Coupler, Adaptor, etc.

CLASSIFICATION: US Class II / EU Class IIa

APPLIED (PERFORMANCE) STANDARDS:

There are no known standards established for powered, simple cranial drills, burrs, trephines, and their accessories at this time. There are no known performance standards for bone mills or adaptors for powering devices for bone mills. Appropriate international accepted standards for materials identification and testing, and Quality /Management Systems are applied.

SUMMARY:

The Coupler is a simple attachment; comprised of a cylindrical housing with external locking feature, that when inserted into the bone mill, physically locks the coupler to the bone mill. The coupler is designed to attach and lock onto the Anspach drill motor drive shaft, to permit transfer of motor speed/torque to the bone mill input spindle (drive shaft).

There are two coupler designs; one for Black Max and one for Micro/Max/xMax and eMax.

Attachment is a simple insertion/twist motion, to align cantilever tabs with the Bone Mill "D-lock" feature. Detachment is a simple pull motion that depresses the two coupler cantilever tabs, un-locking coupler from the bone mil for easy removal.

IDENTIFIED ADDITIONAL RISKS:

Locking tab damage or excessive/premature wear:

Appropriate design considerations (materials, design, etc.) for such wear are incorporated and design safety factors exceed predetermined design requirements.

Bone mill design change to inhibit use of the Anspach motor/coupler assembly:

Thought possible, it would be highly unlikely as it would require a similar design revision to all currently distributed Midas Rex Motors and/or bone mills.

INDICATIONS / CONTRAINDICATIONS:

The Anspach Surgical Drill, Specialty Nosepiece Attachment "Adaptor/Coupler" is indicated for use by trained medical personnel as an interface coupling device, to permit attachment to and operation of the Medtronic, Midas Rex "Legend" Bone Mill (BM100) and Disposable Bowl (BM200) with an Anspach motor. It is contraindicated for use by untrained personnel or as a nosepiece attachment for any other competitive device.

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CLEANING/STERILIZATION/MAINTENANCE:

The Anspach Coupler is distributed clean, non-sterilized and is intended to be a re-usable device. The coupler is not expected to be subjected to gross bio-contamination, but contact with soiled gloves could cause external bio-contamination. Validated cleaning, disinfection, sterilization, and routine maintenance recommendations are provided in product use manuals available to all purchasers and Instructions (Directions) For Use (IFU/DFU) that accompany each product.

The Anspach Coupler is not serviceable by user or third parties but remains fully serviceable by Anspach. Unauthorized service/repair activities can invalidate warranty.

WARNINGS and CAUTIONS:

Generic Warnings and Cautions for use of Anspach motor systems, attachments and cutters are specified on product inserts. For safe and effective use of any Anspach product, it is strongly suggested that specialized training be undertaken since surgical techniques using Anspach products are highly specialized and complex procedures. Improper surgical technique or improper use of Anspach products can cause severe injury or death to a user or patient and cause severe damage to Anspach products and/or other equipment.

SUBSTANTIAL EQUIVALENCE:

The Anspach coupler is substantially equivalent to other Anspach Attachments in that it is attached to an Anspach surgical drill motor to accept and support a bone cutting/ processing device (cutter, saw, perforator, chuck system, etc.).

	Anspach Coupler	**Other Anspach Nosepiece Attachments**
Use w/Pneumatic & Electric motors	Y	Y
Tool-Less attachment	Y	Y
For use with Competitor Device(s)	Y	–
Straight Nosepieces:		N
Saggital Saw:		Y
Chuck System:		Y
Speed Reducers:		Y
Input Speed	80-85k	80-85k
Operating temperature (Max)	120° Max	120° Max
Stainless steel construction	Y	Y
Corrosion resistant bearings	Y	Y
Immersion cleaning	Y	Y
Steam Sterilization	Y	Y
Sterrad sterilization	Y	Y
User Service/Repair	N	N
Anspach Service/Repair	Y	Y

End Summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 7 2005

Mr. William G. Conety
Director, Regulatory Affairs and Quality Assurance
Anspach Companies
4500 Riverside Drive
Palm Beach Gardens, Florida 33410

Re: K050628
Trade/Device Name: Adaptor/ Coupler
Regulation Number: 21 CFR 882.4310
Regulation Name: Powered simple cranial drills, burrs, trephines, and their accessories
Regulatory Class: HBE
Product Code: II
Dated: March 7, 2005
Received: March 11, 2005

Dear Mr. Conety:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K050628

510(k) Number: K 050628

Device Name: Adaptor/Coupler

INDICATIONS FOR USE:

The Anspach Surgical Drill, Specialty Nosepiece Attachment "Adaptor/Coupler" is indicated for use by trained medical personnel as an interface coupling device, to permit attachment to and operation of the Medtronic, Midas Rex "Legend" Bone Mill (BM100) and Disposable Bowl (BM200) with an Anspach motor.

Prescription Use: X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-the-Counter Use: _____
(21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

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